

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : FREYNE, et al. Confirmation No.: 7434
Patent No. : 7,655,642
Filed : June 25, 2006
Title : 3-CYANO-QUINOLINE DERIVATIVES WITH ANTIPROLIFERATIVE
ACTIVITY
Art Unit : 1624
Examiner : Noble E. Jarrell

CERTIFICATE OF EFS TRANSMISSION

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being transmitted to the United States Patent and Trademark Office on the date shown below via the "Electronic Filing System" in accordance with 37 C.F.R. § 1.6(a)(4).

Evelina Smith

/Evelina Smith/

March 26, 2010

Type or print name

Signature

Date

Mail Stop Patent Ext.
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**APPLICATION FOR PATENT TERM ADJUSTMENT
UNDER 37 C.F.R. 1.705(d) AFTER PATENT ISSUANCE**

Dear Sir:

Responsive to the Determination of Patent Term Adjustment indicated on the front page of US Patent 7,655,642 (issued February 2, 2010), and in light of the recent ruling in *Wyeth v. Kappos*, No. 2009-1120, slip op. (US Court of Appeal Federal Circuit) the Applicants submit this Request for Reconsideration of Patent Term Adjustment under 37 C.F.R. 1.705. As stated in 37 C.F.R. 1.705(d):

any request for reconsideration of the patent term adjustment indicated in the patent must be filed within two months of the date the patent issued...

This request is being submitted within two months of the issuance of the US Patent 7,655,642 (i.e., on or before April 2, 2010), and complies with the relevant deadline specified in 37 C.F.R. 1.705(d). **Thus, Applicants contend this request is timely.**

1 Payment of fee under §1.18(e)

Applicants hereby authorizes the Patent Office to charge the fee set forth in §1.18(e) and any other fees that may be due to Deposit Account 10-0750/AGK/PRD2168USPCT1.

2. Statement of Facts

Applicants submit that, due to an incorrect PTA calculation under 37 C.F.R. 1.1702(a), and the recent Wyeth decision, the correct Patent Term Adjustment should be at least an additional 226 days of Patent Term Adjustment to be added to the 217 days of Patent Term Adjustment already calculated on PAIR, resulting in a total Patent Term Adjustment of 443 days.

A. "USPTO "A Delay" Calculation

The USPTO's determination of the delay in prosecution, which, for purposes of this request and in keeping with the explanation provided in *Wyeth*, Applicants will refer to as the "A delay. The "A delay" patent term adjustment was determined to be 217 days in the Issue Notification mailed January 15, 2010.

B. "B Delay" Calculation

"B Delays" are defined as delays by the PTO under 35 U.S.C. § 154(b)(1)(B), which guarantees no more than three year application pendency.

37 CFR § 1.702 (b), states:

Subject to the provisions of 35 U.S.C. 154(b) and this subpart, the term of an original patent shall be adjusted if the issuance of the patent was delayed due to the failure of the Office to issue a patent within three years after the date on which the application was filed under 35 U.S.C. 111(a) or the national stage commenced under 35 U.S.C. 371(b) or (f) in an international application, but not including: (1) Any time

consumed by continued examination of the application under 35 U.S.C. 132(b); (2) Any time consumed by an interference proceeding under 35 U.S.C. 135(a); (3) Any time consumed by the imposition of a secrecy order under 35 U.S.C. 181; (4) Any time consumed by review by the Board of Patent Appeals and Interferences or a Federal court; or (5) Any delay in the processing of the application by the Office that was requested by the applicant.

When calculating "B Delay", application pendency is measured from the date that is three years after the date that the application was filed. National Stage under 35 U.S.C. 371(c) for this application commenced on June 15, 2006, and the date that is "three years later" is June 15, 2009. The above-captioned application issued on February 2, 2010, which is 232 days after the three-year pendency date of June 15, 2009.

The B period does not include, however, any applicant delays, of the following:

- (1) Any time consumed by continued examination of the application under 35 U.S.C. 132(b);
- (2) Any time consumed by an interference proceeding under 35 U.S.C. 135(a);
- (3) Any time consumed by the imposition of a secrecy order under 35 U.S.C. 181;
- (4) Any time consumed by review by the Board of Patent Appeals and Interferences or a Federal court; or
- (5) Any delay in the processing of the application by the Office that was requested by the applicant.

None of the above delays occurred in the instant application. Thus, the above captioned application has a "B" delay, resulting from the application pending longer than three years, of 232 days.

C. "B Delay" Calculation Must be Added to the "A Delay" Calculation

This application has issue as a U.S. Patent on February 2, 2010 and nothing has occurred to cut off any further patent term adjustment that would otherwise accrue under 37 C.F.R. §1.702(b). The Patent Office however has **not** included in the Patent Term Adjustment the days

related to the “B delay,” which are the days delay resulting from an application pending longer than three years. According to 37 C.F.R. 1.703(b):

The period of adjustment under § 1.702(b) is the number of days, if any, in the period beginning on the day after the date that is three years after the date on which the application was filed under 35 U.S.C. 111(a) or the national stage commenced under 35 U.S.C. 371(b) or (f) in an international application and ending on the date a patent was issued...

The *Wyeth* decision states that the Federal Circuit affirmed the District Court’s decision which held that “the ‘A period’ and ‘B period’ overlap only if they occur on the same calendar day or days” (D.D.C. Sept 30, 2008, No. 07-1492, slip op. at 8).

Thus, according to the *Wyeth* decision, Applicants are entitled to both the “A delay” of 217 days and the “B delay” of 232 days minus any overlap that occurs on the same calendar days.

According to the PAIR information, and the above dates, there is an overlap of 6 calendar days between the “A delay” (217 days) and the “B delay” (232 days).

The “A” delay of 304 days occurred between August 18, 2007 (the date that is 14 months after June 18, 2006, the date the application fulfilled the requirements of 35 USC 371) and June 17, 2008, the mailing date of the first substantive office action.

The “A” delay of 6 days occurred between August 27, 2009 (the date that is 4 months after Applicant’s April 27, 2009 Reply after Non-Final Action under 37 C.F.R. 1.111) and September 2, 2009, the mailing date of the Notice of Allowance.

The “B” delay of 232 days occurred between June 15, 2009 (the date that is 3 years after June 15, 2006, the filing date of the application) and February 2, 2010, the issuance of the patent.

Thus, there is an overlap of the “A” delay of 6 days (running from August 27, 2009 to September 2, 2009) with the “B” day (running from June 15, 2009 to February 2, 2010).

Accordingly, the Patent Term Adjustment for this case should be 217 days of “A” delay, plus 232 days of “B” delay, minus 6 days of overlap, which equals 443 days.

3. Other Circumstances

As required under 37 C.F.R. §1.705(b)(2)(iii) and (iv)(B), Applicant states:

(1) this application is not subject to a Terminal Disclaimer; and

(2) confirms that except for the Applicant’s delay periods as acknowledged by the Patent Office in its calculation of the “A” delay, there were no other circumstances constituting a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in § 1.704.

4. Conclusion

In light of the foregoing, the Applicants respectfully request that an additional 226 days of Patent Term Adjustment to be added to the 217 days of patent term adjusted already calculated on PAIR, resulting in a total Patent Term Adjustment of 443 days.

If a telephone conference would expedite the prosecution of this Request for Reconsideration of Patent Term Adjustment, please contact the undersigned agent as indicated below.

Respectfully submitted,

/Alana G Kriegsman/

By: _____
Alana G. Kriegsman, Reg. No. 41,747

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-1495
Dated: March 26, 2010